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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,563	02/28/2002	Alberto Siccardi	113957-260	5126

7590 08/02/2002

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EXAMINER

HARMON, CHRISTOPHER R

ART UNIT PAPER NUMBER

3721

DATE MAILED: 08/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/087,563

Applicant(s)

SICCARDI, ALBERTO

Examiner

Christopher R Harmon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 5, 7, and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The group of "distilled water, physiological solutions and hydrogen peroxide" (claim 5, line 2) is not disclosed in the specification.

"A means that includes a nozzle that is moved by a double-effect piston controlled by a sensor, and that is supplied with a lance for penetration into the valve cavities" (claim 7, lines 3-4) is also absent from the specification.

"a flusstate" (claim 7, line 2); and "a piezoelectric transducer" (claim 15, line 3) are not described in the specification.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following phrases are considered indefinite:

"4rtical" (see claim 2, line 2).

"with procedures substantial y equal to those of" (claim 3, last line).

"liquid being detected b a circuit" (claim 7, last line).

"shaping at a transversal welding o the bag" (claim 14, line 2).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-2, 7, 9, and 13-14 are rejected, as best understood, under 35

U.S.C. 103(a) as being unpatentable over Baldini et al. (US 4,656,813) in view of Fabricius (US 5,069,017) and further view of Takagaki et al.

Baldini et al. teach a method for the manufacture and fillings of flexible sterilizable bags comprising printing 2, cleaning 3, and sterilizing of a film 4; aligns the film 4d; welding the film to form a bag 5; welding a valve to the film bag 5b; dosing the bag DOS; filling the bag STO; (figure 2).

In operation, the system forms, sterilizes, fills, and seals printed flexible bags with valves attached. Because the applicant is one of the common inventors of US Patent 4,656,813, the invention and its operation are not discussed here, rather only the

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improvements upon the invention as understood by the examiner. Baldini et al. do not describe certain limitations claimed by the applicant as improvements upon the commonly owned invention; such as dry cleaning the printed film, humidifying the valve cavity, or using control algorithms for shaping and welding the bags (claim 13). As an additional note, the limitation of gimbal aligning (claims 1) is considered anticipated by Baldini et al. (US 4,656,813) in alignment roller 4d (figure 3).

Fabricius teaches a dry cleaning procedure of a packaging film (column 2, lines 19-53) in an aseptic filling machine for food. It would have been obvious to one of ordinary skill in the art at the time of the invention to include the dry cleaning procedure as taught by Fabricius in the invention of Baldini et al. in order to free the packaging film of foreign substances.

Takagaki et al. teach a process for producing a self supporting package having an outlet stopper and an apparatus for producing said package comprising welding heads 45 and 49 (figure 14) controlled by an algorithm and sensor controls (column 20, lines 12-62). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the algorithm control means as taught by Takagaki et al. in the modified invention of Baldini et al.

Regarding claim 12, Takagaki et al. also teach suspension holes in an embodiment of the bag, seen in figure 8 at the bottom corners of the bag. Therefore, it would also have been obvious to include the suspension holes in the bag for further uses; (ie. stationary suspension, transport, etc.).

7. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. (US 4,656,813) in view of Fabricius (US 5,069,017) and Takagaki et al. as applied to claims 1-2, 7, 9 and 13-14 above, and further in view of Duffey et al. (US 5,129,212).

The modified invention of Baldini et al. does not indicate sterilizing the spouts prior to application to the flexible bag material. Duffey et al. teach a method and apparatus for automatically filling and sterilizing containers in which spouts S are moved along tunnel 122 and sterilized by hydrogen peroxide gaseous medium (column 10, line 7 - column 11, line 33; figures 10-14).

It would have been obvious to one of ordinary skill in the art at the time of the invention to sterilize the spouts prior to applying them to the bag material as taught by Duffey et al. in the modified invention of Baldini et al. in order to maintain a sterile environment throughout the bag manufacturing procedure.

The modified invention of Baldini et al. does not indicate a contribution regulation valve, a constant pressure valve, and a flowmeter. It would have been obvious to one of ordinary skill in the art to include a constant pressure valve for adjusting/regulating the pressure of the system as is well known in the art.

Duffey et al. teach a volume flow meter (not shown) and contribution regulation valve (single head filler valve) 186 operating in a pressurized system (column 13, lines 1-12). A predetermined amount of filling liquid is supplied to the bags accurately.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include the flowmeter and valve as taught by Duffey et al. in the modified invention of Baldini et al. to accurately fill the bags.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. (US 4,656,813) in view of Fabricius, Takagaki et al., and Duffey et al. as applied to claims 3-5 above and further in view of Madsen (US 3,451,403).

The modified invention of Baldini et al., in both instances above, does not disclose detecting electric conductability of the sanitizing solution. Madsen teaches a method and apparatus for determining the purity of a flowing solution or mixture in which "A stream of the solution or mixture is fed into a container after which a diluting or concentrating agent is fed into the container, and measuring means continuously measures the conductivity of the contents of the container." (abstract of the disclosure, lines 3-7). Automatic control means are provided "to switch the feed back to the solution or mixture when the conductivity has declined to a predetermined value..." (abstract of the disclosure, lines 10-12).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include a system as described by Madsen in either modified invention of Baldini et al. in order to monitor and control the amount of solution being administered to each bag.

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9. Claim 8, 10, and 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. in view of Fabricius, Takagaki et al., as applied to claims 1-2, 7-10, and 12-14 above, and further in view of Ogata (GB 2142282 A).

The modified invention of Baldini et al. does not disclose a "heated" printing procedure. Ogata (GB 2142282 A) teaches an automatic packing machine in which " a heated type is pressed against the receiving roll through the packing sheet and printing tape and packing sheet to apply printing to the packing sheet" (claim 1, lines 6-9). It would have been obvious to one of ordinary skill in the art to include the heated printing procedure in the modified invention of Baldini et al. in order to apply printing to the bag material.

10. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. in view of Fabricius, Takagaki et al., and Ogata, as applied to claims 8, 10, and 12 above, and further in view of Brennan et al. (US 4,587,793).

Regarding the limitation of a suspension ring, modified Baldini et al. do not provide for this feature. Brennan et al. (US 4,587,793) teach a bag with a suspension aperture 178 (figure 7) providing for hanging of the bag during the infusion process (column 8, lines 53-54). It would have been obvious to one of ordinary skill in the art, at the time of the invention, to include the suspension aperture as taught by Brennan et al. in the modified invention of Baldini et al. in order to support the bag during the infusion process.



11. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. (US 4,656,813) in view of Fabricius (US 5,069,017) and Takagaki et al. as applied to claims 1-2, 7, 9, 13-14 above, and further in view of Aindow et al. (US 5,934,043).

The modified invention of Baldini et al. provides a ultrasonic welder 21 but does not disclose specifically a piezoelectric transducer, sonotrode, etc. as in claim 45. Aindow et al. teach a web cutting apparatus comprising a ultrasonically vibrated anvil 12 (sonotrode); position transducers 40; and piezoelectric core 142 (figures 5 and 9). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the various welding elements as taught by Aindow et al. in the modified invention of Baldini et al. in order to seal the web.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

### ***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R Harmon whose telephone number is 703-308-8643. The examiner can normally be reached on Monday-Thursday from 8-6.

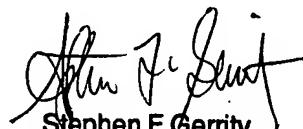
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada can be reached on 703-308-2187. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-305-3579 for regular communications and 703-305-3579 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

ch  
July 25, 2002

  
Stephen F. Gerrity  
Primary Examiner